IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH DIVISION

WILLIAM L. BELL, JR.,	)	**ELECTRONICALLY FILED**
Plaintiff,	)	**Case No. 2:17-cv-01153-JFC**
v.	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG; BOEHRINGER INGELHEIM INTERNATIONAL GMBH; and ELI LILLY & COMPANY,	)	**JURY TRIAL DEMANDED**
Defendants.	)	

DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. AND ELI LILLY AND COMPANY'S BRIEF IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6), Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") and Eli Lilly and Company ("Lilly") (together, "Defendants")[1] submit this Motion to Dismiss Plaintiff's First Amended Complaint ("FAC") for failure to state a claim upon which relief can be granted.

INTRODUCTION

This case arises out of Plaintiff William Bell Jr.'s alleged development of acute kidney injury ("AKI"), which he attributes to his use of Jardiance. Jardiance is a prescription drug approved by the U.S. Food and Drug Administration ("FDA") as safe and effective for the treatment of type 2 diabetes. BIPI holds the New Drug Application ("NDA") for Jardiance, and BIPI and Lilly co-market the product.

Plaintiff originally filed his Complaint on September 1, 2017 [D.E. 1], and BIPI and Lilly jointly moved to dismiss [D.E. 10-11]. On February 15, 2018, the Court dismissed Plaintiff's Complaint in its entirety, allowing Plaintiff leave to amend his negligence- and fraud-based claims [D.E. 21]. On March 8, 2018, Plaintiff filed his FAC [D.E. 22].

The FAC still does not plead a cognizable claim against Defendants, and therefore the FAC should be dismissed in its entirety for failure to state a claim. Plaintiff's failure to warn claim is now premised largely on a theory that the *initial* FDA-approved labeling for Jardiance should have contained different information based on Defendants' alleged knowledge of kidney damage associated with Jardiance, *at the time of* Jardiance's FDA approval in August 2014. But this new claim is preempted. The FDA assessed Jardiance's warning at the time of approval in August 2014, deemed Jardiance safe and effective when accompanied by that warning, and

[1] As of the date of this filing, Defendants Boehringer Ingelheim Pharma GmbH & Co. KG and Boehringer Ingelheim International GmbH have not been served in this action.

required Jardiance to be accompanied by the *precise warning* approved by the FDA at the commencement of marketing, which did not include an AKI warning. Plaintiff's attempt to impose a state law duty to provide a different warning at the time of Jardiance's FDA approval therefore fails.

Other than his preempted failure to warn theory, and notwithstanding the Court's clear direction to include factual allegations, Plaintiff's FAC remains laden with legal conclusions. The few new factual allegations, *see* FAC ¶¶ 19, 34, 41, and minor wording changes do not cure the deficiencies in Plaintiff's remaining claims, and the FAC should be dismissed in its entirety with prejudice.

BACKGROUND

Plaintiff was prescribed Jardiance 25mg to treat his diabetes. *See id.* ¶ 34. Jardiance (*empagliflozin*) was approved by the FDA in August 2014 as safe and effective for the treatment of Type 2 diabetes. *Id.* ¶ 22. It is a member of the class of medications used to treat Type 2 diabetes known as sodium-glucose cotransporter-2 ("SGLT-2") inhibitors. *Id.* ¶ 25. Plaintiff alleges that he began taking Jardiance on June 13, 2015 and experienced AKI on August 31, 2015. *Id.* ¶¶ 34, 38. Despite Plaintiff's alleged injury, he continued to take Jardiance until February 3, 2016. *Id.* ¶ 34. Plaintiff contends that Defendants violated state law because "[a]lthough Defendants knew of the risks for kidney damage associated with taking JARDIANCE in August 2014, the warnings and precautions fail to mention 'acute kidney injury' or a [sic] it was formally known, 'acute renal failure.'" *Id.* ¶ 24.

REGULATORY BACKGROUND

Congress has entrusted to the FDA sole authority to approve prescription drugs for sale in the United States. *See, e.g.*, 21 U.S.C. § 393(b). The Federal Food, Drug, and Cosmetic Act

("FDCA") requires drug manufacturers to gain FDA approval before marketing or selling a new drug in interstate commerce. *Id.* § 355(a). To seek FDA approval of a new drug, a manufacturer must submit a New Drug Application ("NDA"). *See* 21 C.F.R. § 314.1, *et seq.* The FDA approval process is "onerous and lengthy," *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013), and the FDA will refuse to approve a drug if the drug lacks either "adequate tests . . . to show whether or not [the] drug is safe for use" or "substantial evidence that the drug will have the effect it purports or is represented to have." 21 U.S.C. § 355(d)(5).

Under the FDCA, "drug manufacturers must gain approval from [the FDA] before marketing any drug in interstate commerce." *Bartlett*, 570 U.S. at 476 (citing 21 U.S.C. § 355(a)). After FDA approval, the FDCA *prohibits* a manufacturer of a generic or brand-name drug "from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" *Id.* at 472 (citing 21 C.F.R. § 314.70(b)(2)(i)).[2] If a drug's composition is redesigned, "the altered chemical [is] a new drug that would require its own NDA to be marketed in interstate commerce." *Id.* at 484.

"The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009). The NDA must include "the labeling proposed to be used" for the drug, 21 U.S.C. § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(i), and "a discussion of why the [drug's] benefits exceed the risks under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii). To approve an NDA, the FDA must determine, "based on a fair evaluation of all material facts," that the proposed label is not

[2] Moderate changes must be reported to the FDA "at least 30 days *prior* to distribution of the drug product made using the change," 21 C.F.R. § 314.70(c) (emphasis added), while minor changes need only be reported in an annual report to the FDA. *Id.* § 314.70(d)(3).

"false or misleading in any particular," 21 U.S.C. § 355(d)(7), or otherwise "does not comply with the requirements for labels and labeling." 21 C.F.R. § 314.125(b)(8), (b)(6). Once the FDA has approved an NDA, a manufacturer may distribute the drug so long as it uses the FDA-approved label; if it does not do so, it violates federal law. *See* 21 U.S.C. §§ 331(c), 333(a), 352(a), (c).

After FDA approval, there are two ways a manufacturer can change a drug's label. "First, the default rule is that a manufacturer must secure FDA approval for a proposed change prior to distributing the product with the changed label." *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 37 (1st Cir. 2015) (citing 21 C.F.R. § 314.70(b)(2)(v)(A)). Second, under the Changes Being Effect ("CBE") regulation, a drug manufacturer can, without prior FDA approval, make certain types of changes to the drug's label, as long as the drug manufacturer satisfies two requirements. *See* 21 C.F.R. § 314.70(c)(6)(iii). First, the label change must reflect "newly acquired information," which is defined by regulation as

> data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

Id. § 314.3(b). Second, the label change must accomplish at least one of five objectives, including, *inter alia*, "[t]o add or strengthen a . . . warning . . . for which the evidence of a causal association satisfies the standard for inclusion in the labeling." *Id.* § 314.70(c)(6)(iii)(A).

FEDERAL PREEMPTION

The doctrine of preemption arises from the Supremacy Clause of the U.S. Constitution, which provides that the Constitution, federal law, and all treaties are "the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or

Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. Thus, since the Supreme Court's decision in *McCulloch v. Maryland*, it has been settled that state law that conflicts with federal law is "without effect." *Bartlett*, 570 U.S. at 472. Conflict preemption precludes application of state law when it is "impossible for a private party to comply with both state and federal requirements." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 899 (2000).

Three recent Supreme Court decisions have outlined the test for conflict preemption in pharmaceutical drug cases. In *Wyeth*, the Court explained that the impossibility variety of conflict preemption does *not* exist where a federal regulatory provision expressly allows a manufacturer to unilaterally do what state law allegedly would require. *See* 555 U.S. at 572-73. In rejecting the manufacturer's preemption defense, the Court reasoned that, *after* receiving FDA approval, the manufacturer could have used the CBE process to update the drug's label when the alleged risks became apparent. *Id.* "By hinging preemption on the availability [to use the CBE process] in a particular case, *Wyeth* effectively reserves the launch of new drugs to the expertise of the FDA." *In re Celexa*, 779 F.3d at 41.

Then, in *Mensing*, the Court clarified that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it," defining independently to mean unilaterally, "without the Federal Government's special permission and assistance." 564 U.S. at 620-24. "The Court thus limited *Levine* to situations in which the drug manufacturer can, 'of its own volition, . . . strengthen its label in compliance with its state tort duty.'" *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 295 (6th Cir. 2015); *see also In re Celexa*, 779 F.3d at 41 (same).

Finally, in *Bartlett*, the Court extended the *Mensing* impossibility preemption test beyond generic drug manufacturers by finding that it would be impossible for a drug manufacturer to

make major changes to a drug's design, "whether generic or brand-name," without the FDA's permission. 133 S. Ct. at 2471. Any such change, the Court held, would render the drug a "new drug" that must receive prior FDA approval before it can be marketed. Thus, *Barlett* confirmed the core holding of *Mensing* that, when a party cannot satisfy its alleged state law duties *before* obtaining the FDA's approval, those state law claims are preempted. "Read holistically," *Wyeth*, *Mensing*, and *Bartlett* "indicate[] that federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication." *Utts v. Bristol–Myers Squibb Co.*, 226 F. Supp. 3d 166, 178 (S.D.N.Y. 2016) (hereinafter "*Utts I*").

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Palakovic v. Wetzel*, 854 F.3d 209, 219 (3d Cir. 2017). "[W]ith respect to mere conclusory statements, a court need not accept as true all of the allegations contained in a complaint." *Bell v. Boehringer Ingelheim Pharm., Inc.,* No. CV 17-1153, 2018 WL 928237, at *2 (W.D. Pa. Feb. 15, 2018). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting the fraud or mistake." Fed. R. Civ. P. 9(b). "A complaint that lumps together numerous defendants does not provide sufficient notice of which defendants allegedly made the misrepresentations." *Kester v. Zimmer Holdings, Inc.*, Case No. 2:10-cv-00523, 2010 WL 2696467, at *14 (W.D. Pa. June 16, 2010).

I. PLAINTIFF'S FAILURE TO WARN AND DESIGN CLAIMS FAIL.

Plaintiff's warnings and design claims are premised on allegations that Defendants should have changed the Jardiance label at the time of FDA approval and should have redesigned

Jardiance at some point before Plaintiff's alleged injury.[3] *See* FAC ¶ 24 ("Although Defendants knew of the risks for kidney damage associated with taking JARDIANCE in August 2014, the warnings and precautions fail to mention [AKI] or a [sic] it was formally known, 'acute renal failure.'"); *id.* ¶ 90 ("Defendants made conscious decisions not to redesign" Jardiance). These claims are preempted by federal law, because, as shown below, Defendants could not have changed the Jardiance label or redesigned Jardiance without prior permission from the FDA.

A. Defendants Could Not Have Changed the Jardiance Label Prior to or After FDA Approval.

Plaintiff's Pennsylvania law warnings claims require that he plead facts to plausibly establish that Defendants had a duty to "warn of risks, not generally known and recognized, of which [they] ha[ve] or reasonably should have knowledge." *Hahn v. Richter*, 673 A.2d 888, 890 (Pa. 1996) (emphasis omitted). Plaintiff's claims solely rely on an allegation that "by August of 2014, Defendants knew of the risks for kidney damage associated with taking Jardiance," citing to two internet articles that, like Plaintiff's FAC, contain no factual support for this assertion. FAC ¶ 23. Plaintiff alleges that despite Defendants' knowledge of the "risks for kidney damage associated with taking JARDIANCE in August 2014," *i.e.* the date of Jardiance's approval, "the warnings and precautions fail to mention '[AKI]' or a [sic] it was formally known, 'acute renal failure.'" *Id.* ¶ 24. In other words, Plaintiff alleges that BIPI should have provided a different label at the time of Jardiance's approval by the FDA.

Defendants could not have done so pursuant to federal law, however. The FDA approves

[3] Lilly is filing a separate Motion to Dismiss all claims against it on preemption grounds, on the basis that it could not have changed Jardiance's label or design because it does not and has never held the Jardiance NDA. Lilly's Motion to Dismiss also challenges the absence of any allegations in the FAC as to Lilly's role in the design of Jardiance, despite clear direction from the Court that any Amended Complaint by Plaintiff should delineate the roles of each Defendant in Jardiance's design.

a drug *only* if it determines that the drug is safe for use under its proposed labeling and that the probable therapeutic benefits outweigh its risks of harm. 21 U.S.C. § 355(d). In *Wyeth*, the Supreme Court made clear that "[t]he FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." 555 U.S. at 568. Here, on approval, the FDA commanded that the "[c]ontent of labeling must be identical to the enclosed labeling." Jardiance NDA Approval Letter (Aug. 1, 2014) at 1.[4] Thus, Defendants would have violated federal law (*i.e.*, Jardiance would have been misbranded) if, on approval, Defendants instead had marketed Jardiance with labeling other than precisely what the FDA approved. *See* 21 U.S.C. §§ 331(c), 333(a), 352(a), (c).

Accordingly, federal law preempts Plaintiff's claims that Defendants should have provided an AKI warning upon first marketing Jardiance. *See, e.g.*, *Utts I*, 226 F. Supp. 3d at 184-85 (holding that warnings claim premised on adequacy of label as approved by FDA when drug was first marketed was preempted, because plaintiffs did not plead "newly acquired information" that would have allowed manufacturer to independently change warning label); *accord MacMurray v. Boehringer Ingelheim Pharm. Inc.*, No. 2:17-cv-00195-JNP-DBP, [D.E. 37] at 10 (D. Utah Dec. 6, 2017) (Ex. B) (hereinafter "*MacMurray* Order"); *McGee v. Boehringer Ingelheim Pharm. Inc.*, No. 2:16-cv-02082-KOB, [D.E. 30] (N.D. Ala. March 20, 2018) (Ex. C) (hereinafter "*McGee* Op.") at 6-7; *Mitchell v. Boehringer Ingelheim Pharm., Inc.*, No. 116CV02384STAEGB, 2017 WL 5617473, at *4 (W.D. Tenn. Nov. 21, 2017) ("any claim .

[4] *At* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/204629Orig1s000ltr.pdf (last visited March 21, 2018) and attached hereto as Ex. A. On a motion to dismiss, a court may consider the allegations in the complaint, along with any exhibits attached to the complaint and matters of public record, including FDA-approved prescription drug labeling. *Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 750-51 (W.D. Pa. 2011).

. . based on the alleged inadequacy of the initial FDA approved label fails as a matter of law because Defendant was required to use that label when it first marketed Jardiance"); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, 185 F. Supp. 3d 761, 769-70 (D.S.C. 2016) (because "the FDA approved the Lipitor label" and "specifically approved [a particular] statement," in the label, federal law preempted the claim that "label should have included different statements"). The notion that state law required a different warning to be provided at the time of FDA approval directly challenges aspects of the drug that the FDA expressly approved, and from which Defendants could not deviate. Such state law claims are preempted because they would render the FDA's initial drug approval all but meaningless. *Utts I*, 226 F. Supp. 3d at 184 (finding failure-to-warn claims premised on adequacy of label as approved by FDA when drug was first marketed preempted, because labeling is "[t]he centerpiece of risk management for prescription drugs" and "reflects thorough FDA review of the pertinent scientific evidence"). As the First Circuit summarized, the FDA is the "exclusive judge" of "how a drug can be marketed" on approval. *In re Celexa*, 779 F.3d at 41. Thus, state law claims like those here are preempted because brand name drug manufacturers lack the authority under federal law to alter a label's warnings "at the time the NDA process concludes," because "[t]hey have received approval only for that formulation and that label that survive the NDA process." *Utts I*, 226 F. Supp. 3d at 182.

Nor can Plaintiff claim that Defendants should have changed the Jardiance label *after* FDA approval, pursuant to the CBE process. *See* FAC ¶ 49 (generally discussing a manufacturer's duty to revise its label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"). Plaintiff's FAC does not even mention the CBE process or otherwise articulate a single fact that might constitute "newly

acquired information" on which Defendants could have premised a CBE change to the Jardiance label after FDA approval. *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 660-61 (S.D.N.Y. 2017) (hereinafter "*Utts II*"). Therefore, any argument that Defendants should or could have changed the Jardiance label *after* FDA approval is implausibly pled and should be disregarded. *See, e.g.*, *MacMurray* Order (Ex. B) at 15 (dismissing failure to warn claims where, "the allegations in the complaint, taken as true, only hint at newly acquired information or new analyses"); *McGee* Op. (Ex. C) at 8-9 (dismissing failure to warn claim that did not "specify whether any *new* . . . adverse event reports occurred after Jardiance's approval and before [plaintiff's] harm") (emphasis in original); *Utts I*, 226 F. Supp. 3d at 185 (finding "threadbare" allegation that "[b]efore and after marketing [drug], [d]efendants became aware of many [adverse events reports] in users of its drug" did not identify newly acquired information); *Utts II,* 251 F. Supp. 3d 644, 660-61 (finding documents, including report that analyzed adverse event data in FDA database for drug class including drug at issue, did not constitute "newly acquired information" and therefore dismissing failure to warn claims).

Plaintiff's failure to warn claims should be dismissed with prejudice as a result.

B. Plaintiff's Design Claims Require a Change to Jardiance's Design That Federal Law Forbids.

Plaintiff's design claims are preempted because neither BIPI nor Lilly could independently change Jardiance's FDA-approved design. The Court did not conclusively rule on Lilly's argument that Plaintiff's design claims were preempted, because it dismissed those claims as insufficiently pled. *Bell*, 2018 WL 928237, at *7. Plaintiff's FAC continues to lack facts sufficient to state a design claim as discussed in more detail *infra* at 12-13. But even if Plaintiff had included facts in support of his design claims, these claims are preempted by federal law.

As explained *supra* at 3, brand name manufacturers are prohibited from making major

changes to a drug's design or formulation unless the FDA provides prior approval of those changes. Accordingly, state law design defect claims that place a duty on manufacturers to render a drug safer by altering its composition are preempted by the FDCA. *Bartlett*, 570 U.S. at 490; *see also Yates*, 808 F.3d at 298 (finding design defect claim "clearly preempted by federal law" because "defendants could not have altered the dosage of estrogen" in the birth control patch at issue without first obtaining the FDA's approval of such a design); *Utts I*, 226 F. Supp. 3d at 186 (dismissing negligent design claim on preemption grounds, concluding that "defendants had no ability to alter [the] composition [of the drug] without prior approval of the FDA," pursuant to 21 C.F.R. § 314.70(b)(2)(i)); *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 833-34 (W.D. Tenn. 2016) (dismissing negligent design claim on preemption grounds).

But a major change to Jardiance's design is precisely what Plaintiff purports to require here through the application of state law. Plaintiff's *only* suggestion regarding how Defendants could have alternatively designed Jardiance to avoid the alleged risk of AKI is that Defendants should have designed a different product entirely. *See* FAC ¶ 41 ("Consumers . . . have several alternative safer products available to treat the condition, including metformin, Diabinese, Amaryl, or Glucotrol."). According to federal regulation, however, such a change to the "drug substance" or "drug product" is a major change to Jardiance that requires prior FDA approval of such a design, therefore preempting Plaintiff's design claims. 21 C.F.R. § 314.70; *Yates*, 808 F.3d at 296. Such a conclusion is equally applicable on a motion to dismiss, since no amount of discovery will alter the fact that any design change would necessarily require prior FDA approval. *Fleming*, 186 F. Supp. 3d at 833-34; *Utts I*, 226 F. Supp. 3d at 186 *cf. Bell*, 2018 WL 928237, at *6 (questioning whether *Yates* court would have ruled similarly on a motion to dismiss).

Even if Plaintiff had pled facts to support a claim that Defendants should or could have changed the Jardiance design—and as explained *infra* at 12-13 and in Lilly's brief—Plaintiff has failed to allege *any* facts as to why Jardiance's design was allegedly defective, how such alleged defects contributed to his injury, or why alternative products are allegedly safer. Plaintiff's claim would nonetheless be preempted because a different formulation of Jardiance would be an entirely different medication subject to separate FDA approval. *Bartlett*, 570 U.S. at 483-84.

II. PLAINTIFF'S FAC FAILS BECAUSE IT REMAINS INSUFFICIENTLY PLED.

The rest of Plaintiff's FAC does not fix the problems documented in the Court's Order on Defendants' original Motion to Dismiss and should be dismissed for failure to include sufficient facts in support of his claims as stated below.

A. Plaintiff's Negligent Design Claim Fails (Count IV).

To state a claim for negligent design under Pennsylvania law, Plaintiff must show: "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." *Salvio*, 810 F. Supp. 2d at 752 (quoting *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 749 (W.D. Pa. 2011). Plaintiff must also plead that "an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered." *Id.* at 754.

In its Order, the Court highlighted Plaintiff's failure to plead "how and why" Jardiance's design was defective. *Bell*, 2018 WL 928237, at *5. Plaintiff's FAC, however, continues to rely on the same allegations regarding "how SGLT2 inhibitors like Jardiance work," failing to add any facts regarding "why this design is defective." *Id.*; *compare* Compl. ¶¶ 22-24 *with* FAC ¶¶ 25-27. Plaintiff's failure to discuss Jardiance's allegedly defective design "in any level of meaningful detail" requires dismissal of his claim. *Smith v. Howmedica Osteonics Corp*., 251 F. Supp. 3d 844, 854 (E.D. Pa. 2017); *see also Fleming*, 186 F. Supp. 3d at 835 (dismissing design

claim that generically described SGLT2 inhibitors' mechanism of action); *House v. Bristol-Myers Squibb Co.,* No. 3:15-CV-00894-JHM, 2017 WL 55876, at *3 (W.D. Ky. Jan. 4, 2017) (same).

Plaintiff's new allegation that "metformin, Diabinese, Amaryl, or Glucotrol" are "alternative safer products available to treat the condition" comes no closer to stating a safer alternative design as required under Pennsylvania law. FAC ¶ 41. As Judge McVerry and several other courts have held, "'an alternative design must not be an altogether essentially different product.'" *Salvio v. Amgen Inc.*, No. 2:11-CV-00553, 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012) (collecting cases). Plaintiff "merely lists completely different drugs that [he] could have taken," failing "to allege any alternative ways in which [Jardiance] could have been designed," requiring dismiss of his claim. *Id.* Moreover, Plaintiff has not, as the Court instructed, explained why these products "are safer." *Bell*, 2018 WL 928237, at *5.

B. Plaintiff Fails to Allege Facts to Make His Negligence Claim Plausible (Count I).

To plead negligence under Pennsylvania law, Plaintiff must show "that the manufacturer owed a duty to the plaintiff; that the manufacturer breached that duty; and such breach was the proximate cause of plaintiff's injuries." *Salvio*, 810 F. Supp. 2d at 752.

To the extent that Plaintiff's negligence claims are premised on an alleged failure to warn about Jardiance's alleged risk of AKI, Plaintiff has not alleged how an AKI-related warning "would have prevented his physician from prescribing [Jardiance] resulting in a prevention of his injury." *Bergstresser v. Bristol-Myers Squibb Co.*, No. CIV.A. 3:12-1464, 2013 WL 6230489, at *5 (M.D. Pa. Dec. 2, 2013). Moreover, Plaintiff's warnings claim fails to the extent that it is premised on a failure to warn Plaintiff's prescribing physician about a purported risk of "diabetic ketoacidosis, kidney damage, . . . stroke, and heart attack." FAC ¶ 3. Plaintiff only alleges that

he experienced AKI. *Id.* ¶ 38. Plaintiff's claims premised on a failure to warn of unnamed "other related health complications," *see e.g.*, *id.* ¶ 68, similarly fail. *See Mitchell*, 2017 WL 5617473, at *9 (dismissing claim based on "unspecified health related problems").

To the extent that Plaintiff's claim is premised on Defendants' alleged failure to properly design Jardiance, *see* FAC ¶¶ 54, 58, 61-62, it fails for the reasons stated *supra* at 12-13.

Plaintiff's negligence claim purportedly based on an alleged manufacturing defect, *see* FAC ¶¶ 54, 58, 61-62, also fails, because the FAC does not contain "any factual allegations as to *how* Defendants breached any such duty or *how* any such breach caused [his] purported injuries." *House*, 2017 WL 55876, at *5; *accord Salvio*, 810 F. Supp. 2d at 754.

Finally, Plaintiff's claim premised on Defendants' failure to adequately test Jardiance, *see, e.g.,* FAC ¶ 63(a)-(c), must be dismissed because Pennsylvania courts have explicitly stated that negligent failure to test is not a viable cause of action, and "have found no 'duty to test' that would be the basis of such a claim." *Viguers v. Philip Morris USA, Inc.*, 837 A.2d 534, 541 (Pa. Super. Ct. 2003), *aff'd*, 881 A.2d 1262 (Pa. 2005). To the extent that Plaintiff's claim depends on some other theory regarding Defendants' negligent marketing of Jardiance, *see, e.g.*, FAC ¶¶ 54, 61-62, 63(h), Plaintiff has failed to plead any facts supporting such a theory.

C. Plaintiff's Fraud Claims Remain Insufficiently Pled (Count II-III, V-VI).

Plaintiff's FAC does not come any closer to stating "with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Despite the Court's ruling that Plaintiff's fraud-based claims fell "far short of the Rule 9 standard," *Bell*, 2018 WL 928237, at *6, Plaintiff's FAC does not plead any additional facts in support of his fraud-based claims, including each Defendant's role in the alleged fraud, "the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into [his] fraud allegation[s]." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007); *see also MDNet, Inc. v. Pharmacia Corp.*, 147 F.

App'x 239, 245 (3d Cir. 2005) ("the complaint must plead with particularity by specifying the allegations of fraud applying to each defendant"); *Kester*, 2010 WL 2696467, at *11 (dismissing fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraud claims for failure to satisfy Rule 9(b)).

CONCLUSION

For the reasons outlined above, Plaintiff's FAC fails and should be dismissed in its entirety.

Dated: March 22, 2018

Respectfully submitted,

/s/ Wendy West Feinstein

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CERTIFICATE OF SERVICE

I certify that on March 22, 2017, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all registered users, including the below-listed counsel of record:

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